

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ITV DIRECT, INC.,)
)
Plaintiff,)
v.)
)
HEALTHY SOLUTIONS, LLC,)
)
Defendants.)

CAPPSEALS, INC.,)
)
Plaintiff-in-Intervention)
v.)
)
HEALTHY SOLUTIONS, LLC, d/b/a)
DIRECT BUSINESS CONCEPTS; ITV)
DIRECT, INC., AND DIRECT)
FULFILLMENT, LLC.,)
)
Intervenor-Defendants.)

C. A. No. 04-CV10421-JLT

EXHIBIT D

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FILED
CLERK'S OFFICE
AUG 31 2005 4 11:46
DISTRICT COURT
DISTRICT OF MASS

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

DIRECT MARKETING CONCEPTS, INC., et al.,

Defendants.

Civ. No. 04-11136-GAO

**SUPPLEMENTAL MEMORANDUM IN SUPPORT OF PLAINTIFF FEDERAL TRADE
COMMISSION'S MOTION FOR A MODIFICATION OF THE JUNE 23, 2004
PRELIMINARY INJUNCTION AS TO DEFENDANTS DIRECT MARKETING
CONCEPTS, INC., ITV DIRECT, INC., AND DONALD W. BARRETT
AND REQUEST FOR EXPEDITED TREATMENT**

I. INTRODUCTION

In the four weeks since the July 25, 2005 status conference in this case, Defendants ITV Direct, Inc. ("ITV"), Direct Marketing Concepts, Inc. ("DMC"), and Donald W. Barrett ("Barrett") have disregarded the findings of their industry's self-regulatory body, been expelled from their trade association, and disseminated a new infomercial that violates the Preliminary Injunction issued by this Court last year. Their behavior cries out not only for the appointment of a receiver, but also for sanctions. Accordingly, the Federal Trade Commission respectfully submits this Supplemental Memorandum in order to update the Court on these recent developments that bear directly on the merits of the Commission's pending Motion for a Modification of the June 23, 2004 Preliminary Injunction as to Defendants Direct Marketing Concepts, Inc., ITV Direct, Inc., and Donald W. Barrett and Request for Expedited Treatment ("Motion for Modification of the Preliminary Injunction") [Dkt. # 68].

II. OVERVIEW OF THE COMMISSION'S MOTION

In its Memorandum In Support of Plaintiff Federal Trade Commission's Motion for a Modification of the June 23, 2004 Preliminary Injunction as to Defendants Direct Marketing Concepts, Inc., ITV Direct, Inc., and Donald W. Barrett and Request for Expedited Treatment ("FTC Initial Memorandum") [Dkt. # 70], the Commission specifically addressed, among other things, the health and disease claims made by Defendants DMC, ITV, and Barrett (hereafter, jointly referred to as "Defendants"), in two infomercials they had begun airing since the issuance of the Preliminary Injunction: Sea Vegg and Renuva.

In its June 24, 2005, Reply Memorandum in Support of Plaintiff Federal Trade Commission's Motion for a Modification of the June 23, 2004 Preliminary Injunction as to Defendants Direct Marketing Concepts, Inc., ITV Direct, Inc., and Donald W. Barrett and Request for Expedited Treatment ("FTC Reply Memorandum") [Dkt. # 94], the Commission reviewed the Electronic Retailing Self-Regulation Program's ("ERSP") June 2005 decision on the Sea Vegg infomercial. FTC Reply Memorandum, at 4-5.¹ The Commission also related how the Defendants had misrepresented to the Court both ERSP's position on the Sea Vegg infomercial and their own response to ERSP's April 2005 decision on the Renuva infomercial. *Id.* at 11-13.

On July 25, 2005, the Court convened a status conference, during which it scheduled a hearing on the Commission's motion for September 20, 2005. There was no significant discussion of the merits of the Commission's motion during the status conference. The

¹ The ERSP is the electronic direct-response industry's self-regulatory forum. It was created by the Electronic Retailing Association in an effort to improve business practices within the electronic retailing industry.

Defendants did inform the Court, though, that notwithstanding ERSP's conclusion that the Sea Vegg infomercial should be modified substantially or discontinued, they were going to continue running it without making any modifications.

III. RECENT EVENTS THAT FURTHER DEMONSTRATE THE NEED FOR A RECEIVER

The Commission has previously noted to the Court that the Defendants' behavior indicates that they are unwilling or unable to resist making unsubstantiated health claims, and that their repeated misrepresentations to both the Commission and the Court demonstrate that, absent appointment of a receiver, they can be expected to continue to violate the law and injure consumers. FTC Initial Memorandum, at 27, 29-30; FTC Reply Memorandum, at 13-14.

That conclusion has only been reinforced in the weeks since the status conference. First and foremost, the Defendants have now violated the Preliminary Injunction's clear and unambiguous prohibition on claims that a product containing any ingredient in the proprietary blend of Supreme Greens with MSM "is an effective treatment, cure, or preventative for arthritis." Preliminary Injunction as to Defendants Direct Marketing Concepts, Inc., ITV Direct, Inc., and Donald W. Barrett ("Preliminary Injunction"), at 17 [Dkt. #32]. Furthermore, despite their previous assertions that they were cooperating with their industry self-regulatory body, they have now rejected that body's recommendations concerning the Sea Vegg infomercial, and gone so far as to assert that it is this Court that is preventing them from modifying that infomercial. Finally, the Electronic Retailing Association has just expelled ITV from its membership ranks.

These recent developments provide additional evidence of the Defendants' untrustworthiness and their blatant disregard not only for consumers, but also for this Court. In short, they demonstrate the need for appointment of a receiver during the pendency of this

litigation in order to prevent further consumer injury, as well as for any additional relief deemed appropriate by the Court in light of the Defendants' violation of the Preliminary Injunction.

A. The Defendants' New Flex Protex Infomercial Violates the June 23, 2004 Preliminary Injunction

On approximately July 29, 2005 – just a few days after the status conference – the Defendants released a new infomercial for a dietary supplement called “Flex Protex.” Declaration of Deborah Kelly (“Kelly Declaration”), at ¶ 4 and Attachment 3. The infomercial claims, among other things: (1) that Flex Protex is a natural COX-2 inhibitor that effectively relieves the pain associated with, among other diseases, arthritis, rheumatoid arthritis, fibromyalgia, and gout; (2) that it enables the body to regenerate torn cartilage; (3) that not only does Flex Protex not have the health risks associated with other COX-2 inhibitors, such as Vioxx, but it actually improves cardiovascular health; (4) that it prevents arthritis; (5) that clinical studies prove the product's efficacy in reversing cardiovascular disease, and rebuilding cartilage; and (6) that it is good for people of any age, including children. *Id.*, Attachments 1 and 2 at 3-4, 5-6, 9-10, 11-12, 16, 20, 26, 27, 31-32.²

² The infomercial opens with Donald Barrett's now familiar statement about the controversial nature of the program and the litany of the diseases that Flex Protex purportedly treats:

DONALD BARRETT: Hello, my name is Donald Barrett and welcome back to a very controversial edition of ITV.

ON SCREEN: The program you are watching is a paid advertisement for Flex Protex.

DONALD BARRETT: On our show today, we're going to be talking about arthritis and joint health. Many of the drugs presently being used to treat these diseases are being pulled off the market because of the harmful, and sometimes, deadly side effects.

(continued...)

The Defendants' release of yet another infomercial for an ingestible product making health and disease claims while the Court is considering the Commission's Motion for Modification of the Preliminary Injunction would be striking in and of itself. But even more breathtaking is their disregard for the plain language of the Preliminary Injunction, which bars them from making any representation that "Supreme Greens with MSM or any substantially similar product . . . [i]s an effective treatment, cure or preventative for arthritis." Preliminary Injunction, at 17. The Preliminary Injunction also specifically defines the term "substantially similar product" to mean "any dietary supplement containing one or more of the ingredients contained in the proprietary blend of Supreme Greens with MSM." *Id.* at 15.

According to Donald Barrett's "guest" on the new infomercial, Patty McPeak,³ Flex Protex includes, among its ingredients, MSM, and ginger root. Kelly Declaration, Attachment 2, at 18-29. The proprietary formula of Supreme Greens with MSM also contains MSM and ginger root. *Id.* at ¶ 5 and Attachment 4. Thus, Flex Protex is a "substantially similar product" within the meaning of the Preliminary Injunction.

And there can be no question that the Defendants' new infomercial claims that Flex Protex treats, cures and prevents arthritis:

² (...continued)

Today, we're going to be discussing an all-natural alternative to these harmful drugs with Patty McPeak, CEO and founder of Nutracea. Patty has just been granted a patent for an all-natural COX-2 inhibitor. If you suffer from any type of arthritis, osteoarthritis, rheumatoid arthritis, gout or even joint pain, this is a show you're not going to want to miss, so stay with us.

Id. at 3.

³ Ms. McPeak is the founder and Chief Executive Officer of Nutracea, the company that produces Flex Protex. Kelly Declaration, Attachment 2 at 4.

DONALD BARRETT: On our show today, we're going to be talking about arthritis and joint health. . . . If you suffer from any type of arthritis, osteoarthritis, rheumatoid arthritis, gout or even joint pain, this is a show you're not going to want to miss, so stay with us.

DONALD BARRETT: Because a lot of products out there, you know, people have tried products before and, you know, a lot of people say, oh, I've tried things and I've never tried anything natural that really worked. You're pretty confident, in talking to you before the show, that this product works.

PATTY McPEAK: It absolutely works.

ON SCREEN: Results Not Typical

Today's Guest: Patty McPeak, CEO & Founder of Nutracea

Can The Effects of Arthritis Be Relieved Naturally?

DONALD BARRETT: For arthritis, osteoarthritis, even gout.

PATTY McPEAK: Yes, even gout.

DONALD BARRETT: So, let me make sure what you're saying. You're saying this is not only -- acts as a pain reliever by reducing inflammation --

PATTY McPEAK: Right.

DONALD BARRETT: -- but it helps the body rebuild.

PATTY McPEAK: It helps the body regenerate itself.

DONALD BARRETT: Which really gets to the --

PATTY McPEAK: That's right.

DONALD BARRETT: -- root of the problem.

DONALD BARRETT: Well, how long does it take for someone to work? If someone has arthritis right now and they start taking the product, is it going to take two weeks, a month, maybe three months to start working?

ON SCREEN: Results Not Typical

Call 1-800-539-8421 For More Information

Can The Effects Of Arthritis Be Relieved Naturally?

PATTY McPEAK: In some cases, people notice it in the first day or two. It just depends on the uniqueness of each individual. In my case, it took me -- I would say I had about a 50 percent pain reduction in the first two weeks.

DONALD BARRETT: You know, there's millions of people out there suffering. My wife's grandmother, for instance, recently came off of Vioxx, you know, about six months ago when all the news broke. She's in terrible, terrible, terrible pain. You know, she wants to go in and have surgery.

PATTY McPEAK: Take this to her.

DONALD BARRETT: Take this to her?

PATTY McPEAK: Take this to her.

DONALD BARRETT: You're that confident that this can work?

PATTY McPEAK: I am that confident. And I would be very surprised -- it seems to work even more quickly in the elderly. I would be very surprised if she didn't have a very noticeable change within the first week of taking this.

DONALD BARRETT: So, if somebody -- if somebody -- if you have arthritis in your family, can you take this as a preventative for arthritis?

PATTY McPEAK: Oh, it's a wonderful preventative. . . .

DONALD BARRETT: . . . If you have arthritis, osteoarthritis, rheumatoid arthritis, gout, even fibromyalgia, this is a product, I believe, that you cannot live without.

Kelly Declaration, Attachment 2 at 3-4, 9-10, 12, 18-19, 20, 26. Thus, the new infomercial clearly violates Paragraph I of the Preliminary Injunction.⁴

⁴ The Defendants also appear to be violating those portions of Paragraph I that prohibit any representations that a product containing any of the ingredients in the proprietary formula of
(continued...)

And the Defendants should not be heard to argue that their violation of the Preliminary Injunction was inadvertent. In responding to the Commission's Motion, the Defendants stressed their attention to, and compliance with, the Preliminary Injunction. Defendants' Opposition to Plaintiff Federal Trade Commission's Motion for a Modification of the June 23, 2004 Preliminary Injunction as to Defendants Direct Marketing Concepts, Inc., ITV Direct, Inc., and Donald W. Barrett ("Defendants' Opposition"), at 6-7, 10 [Dkt. # 89]. For example, after discussing the review conducted on the Sea Vegg infomercial by both in-house and outside counsel, they stated that "Each of ITV's other infomercials, particularly those advertising any dietary supplement, are required to undergo a similar stringent process of review as to content, claims, disclaimers and scientific support." *Id.* at 10 (noting also "the significant steps taken by ITV to assure compliance with the FTC laws and regulations, as well as this Court's prior Order"). Surely, they could not have overlooked the Preliminary Injunction provisions entitled "Prohibited Business Practices," which specifically detail what representations they can and cannot make in their infomercials. *See* Preliminary Injunction, at 17-18. Moreover, insofar as Barrett and McPeak specifically discuss arthritis and the fact that Flex Protex contains MSM several times during the infomercial, the fact that the ingredients in this new product overlap with those in "Supreme Greens with MSM" and that the disease in question was expressly covered by

⁴ (...continued)

Supreme Greens with MSM (1) is an effective treatment, cure, or preventative for heart disease, or (2) can be taken safely by children. Preliminary Injunction at 17. In addition, they may be violating Paragraph II, which prohibits claims that "Supreme Greens with MSM or any substantially similar product . . . can prevent, treat, or cure any disease, unless, at the time the representation is made, the Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation." *Id.* at 17-18.

the Preliminary Injunction should have been obvious.⁵

B. ERSP Has Referred Sea Vegg to the FTC Because of ITV's Refusal To Comply with ERSP's Recommendations for Modification of That Infomercial

Second, on August 10, 2005, ERSP announced that it had referred the Sea Vegg infomercial to the FTC. Kelly Declaration, at ¶ 7 and Attachment 6.⁶ The press release announcing this referral noted that ERSP had opened a compliance inquiry when it observed the original Sea Vegg infomercial airing six weeks after it had closed its initial inquiry. *Id.*, Attachment 6. Although ITV's initial response to ERSP's compliance inquiry indicated that modifications were being made to the advertising, and that a new version of the infomercial had been sent out for distribution, it subsequently retracted that statement and informed ERSP that it was going to continue running the original infomercial without making any changes to it. *Id.* (Sea Vegg compliance proceeding report).⁷

Indeed, when ITV informed ERSP that it was not going to modify the Sea Vegg infomercial, it represented that its hands were tied as a result of the Court's action. ITV's in-

⁵ The Defendants also may be violating laws enforced by the Food and Drug Administration. In an April 2004 Warning Letter to DMC and ITV concerning Supreme Greens, FDA stated that because Supreme Greens was being promoted for use in the cure, mitigation, treatment or prevention of diseases (including cancer, arthritis, and fibromyalgia), it was deemed a "drug" under the Food and Drug Act; furthermore, it was a "new drug" because it was not generally recognized as safe and effective for its intended uses. Kelly Declaration at ¶ 6 and Attachment 5. The letter went on to say that new drugs may not legally be marketed without prior approval from FDA. *Id.* The same analysis may also be applicable to Flex Protex.

⁶ ERSP had previously referred the Renuva infomercial to the Commission, after ITV continued running it for six weeks after being informed of ERSP's decision. FTC Reply Memorandum, at 12-13.

⁷ Indeed, the Infomercial Monitoring Service reports that Sea Vegg was number 11 on its list of the 100 most frequently aired infomercials in July 2005. Kelly Declaration, at ¶ 8 and Attachment 3. Data for August are not yet available.

house attorney Michael Sciucco stated in an August 3, 2005 letter to ERSP that:

On July 25, 2005, at a hearing before a federal judge in the District of Massachusetts, the FTC discussed with the court its concerns with the Sea Vegg infomercial. ITV responded in open court that it did not intend to stop airing the infomercial. Despite this representation the judge took no action with regard to the Sea Vegg infomercial, instead holding the entire matter over until September 20, 2005.

... [A]s ITV has represented to the FTC and a federal judge; it intends to air the Sea Vegg infomercial in question. While ITV intends to continue to work with ERSP where possible in this case, *ITV has no option but to defer to the judgment of the United States District Court in the District of Massachusetts.*

Kelly Declaration, at ¶ 9 and Attachment 7 (emphasis added). To the contrary, insofar as the Court stated during the status conference that it had not yet read the briefs submitted by the parties on the Commission's Motion, the notion that ITV's ability to modify the Sea Vegg infomercial was constrained by any ruling of this Court is simply false.⁸

C. ITV Has Been Expelled from its Trade Association

Finally, on August 18, 2005, ITV's trade association, the Electronic Retailing Association, announced that ITV Direct had been expelled for noncompliance with the Association's policies and procedures. Kelly Declaration, at ¶ 10 and Attachment 8 at 5. ERA's announcement specifically referenced ITV's conduct concerning the Sea Vegg infomercial. *Id.*

⁸ Mr. Sciucco also stated in this letter that "During [ERSP's initial Sea Vegg inquiry], ITV notified ERSP that the Federal Trade Commission was fully aware of the Sea Vegg infomercial and we were working directly with the FTC to address any concerns." *Id.*, Attachment 7. Although the Commission has no independent knowledge as to whether ITV made such a representation to ERSP at that time, the underlying factual assertion – that ITV was working with the FTC to resolve the Commission's concerns about Sea Vegg – is not true. Commission staff had no communications with ITV concerning Sea Vegg prior to notifying ITV's counsel of our intention to file our Motion for Modification of the Preliminary Injunction, in an effort to have the Defendants agree to submit to a receiver.

IV. APPOINTMENT OF A RECEIVER IS THE ONLY MEANS LEFT TO CONTROL THE DEFENDANTS' BEHAVIOR AND HALT ONGOING CONSUMER INJURY

Consumers are normally protected from misleading advertising by several lines of defense. First, many advertisers participate in industry self-regulatory programs, and comply with the decisions issued by those fora. Second, the FTC enforces federal advertising statutes, which require that advertising be truthful and non-misleading. Finally, the Commission turns to the federal courts when an advertiser is unwilling to agree to comply with the law, or when there are other reasons why judicial intervention is needed to protect consumers.

It is now amply clear that the direct response industry's self-regulatory program cannot adequately protect consumers from these Defendants. Even in the best of circumstances, several months pass between the time ERSP opens an inquiry, and the time it issues its decision; consumers injury continues during this period. Moreover, ITV has now twice delayed removing an ad from the air for weeks after it received ERSP's decision recommending that the infomercial be modified substantially or discontinued. Indeed, the Electronic Retailing Association has now concluded not only that its self-regulatory program cannot effectively rein these Defendants in, but that their conduct is sufficiently egregious that the ITV will no longer be tolerated as an association member.


Nor can the Commission attempt to challenge each new ITV infomercial making disease treatment, cure, and prevention claims. By the time experts in the relevant fields are identified and hired, their reports prepared, and all of the rounds of briefs submitted to the Court, ITV has the benefit of several months of unimpeded access to millions of consumers, many of whom may be particularly vulnerable to smooth sales pitches touting cures for chronic and, in some cases, life-threatening diseases.

In short, this Court is the only entity that can take the steps necessary to ensure that the Defendants comply with the law and do not continue to harm consumers during the pendency of this litigation – by appointing a receiver who can make sure the claims made in each ITV infomercial are truthful and properly substantiated.

V. CONCLUSION

For the foregoing reasons, as well as those set forth in the Commission's two previous memoranda, the Commission respectfully requests that the Court grant its motion to modify the Preliminary Injunction and appoint a receiver over DMC and ITV. The Commission also respectfully submits that the Court take whatever action it deems appropriate to address the Defendants' violation of the Preliminary Injunction.

Respectfully submitted,



DANIEL KAUFMAN
KIAL S. YOUNG (BBO #633515)
EDWARD GLENNON
Federal Trade Commission
600 Pennsylvania Avenue, NW, NJ-3212
Washington, DC 20580
(202) 326-2675, -3126 (voice)
(202) 326-3259 (fax)
dkaufman@ftc.gov or eglennon@ftc.gov
ATTORNEYS FOR PLAINTIFF

Dated: August 24, 2005